

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 17-1255V

UNPUBLISHED

BREANA PORCELLO,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 22, 2020

Special Processing Unit (SPU);  
Findings of Fact; Onset; Influenza  
(Flu) Vaccine; Shoulder Injury  
Related to Vaccine Administration  
(SIRVA)

*Michael G. McLaren, Black McLaren, et al., P.C., Memphis, TN, for Petitioner.*

*Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for Respondent.*

### **DECISION (A) DENYING MOTION FOR SUMMARY JUDGEMENT, AND (B) GRANTING DISMISSAL OF CLAIM<sup>1</sup>**

On September 14, 2017, Breana Porcello filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*<sup>2</sup> (the “Vaccine Act”). Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) as a result of an influenza (“flu”) vaccination administered on November 22, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

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<sup>1</sup> Because this unpublished ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). I intend to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Ms. Porcello moved for summary judgement on May 22, 2019. Motion for Summary Judgement, ECF No. 47. On January 6, 2020, Respondent filed his Response to Summary Judgment, and cross-moved for dismissal of Petitioner's case. ECF No. 60.

For the reasons stated below, Petitioner's motion for summary judgement is denied. Further, I conclude that Petitioner has failed to offer preponderant evidence sufficient to satisfy all of the three *Althen* prongs. Therefore, the petition is dismissed for insufficient proof.

## **I. Factual History**

Ms. Porcello received a flu vaccination on November 22, 2016, in her left shoulder. Ex. 2 at 11. At the time of vaccination, Ms. Porcello was a twenty-year old college sophomore and field hockey player. *Id.* at 10; Ex. 1 at 2. In her affidavit, Ms. Porcello stated that while she suffered no pain or injury to her left shoulder prior to her vaccination, after its administration she experienced immediate pain. Ex. 1 at 1-2. Ms. Porcello also stated that, because she was away at college, she initially sought treatment from her athletic trainer through her campus's health services department. *Id.* at 2. This statement is corroborated in Hilary Ann Turner's affidavit. Ex. 13. In it, Ms. Turner stated that she served as a Certified Athletic Trainer at Ms. Porcello's college and remembered speaking with her in January 2017 about her shoulder pain. *Id.* at 2. Specifically, she recalled that Ms. Porcello "had begun to have left shoulder pain in late 2016." *Id.* Further, in a March 22, 2017 note, Ms. Turner documented that "after winter break," Ms. Porcello "asked about some left upper arm pain she had been experiencing" that was most noticeable when lifting or doing pushups. Ex. 9 at 1.

On January 18, 2017, Ms. Porcello presented to Lawrence Memorial Healthcare Center with complaints of cough, fever, and chills. Ex. 3 at 4. The medical note documenting this visit does not give any indication that Ms. Porcello mentioned suffering from shoulder pain. *Id.* at 3-5. Moreover, under musculoskeletal findings it is noted: "[r]ange of motion grossly normal. No pain with range of motion." *Id.* at 4. Despite this reported finding, Ms. Porcello stated that her range of motion was not examined during this appointment. Ex. 12 at 1 (Petitioner's third affidavit). Ms. Porcello further stated that she informed the treating physician that her shoulder pain had been bothersome since she received the flu shot "a few months back." *Id.* at 1-2.

Almost two months later, on March 17, 2017, Ms. Porcello presented to Dr. Laura L. Carman, her primary care physician, with complaints of left arm pain. Ex. 2 at 6. The medical note indicates that Ms. Porcello "had flu shot in November – has had pain in arm since then." *Id.* It is also noted that Ms. Porcello was seen by her trainer and "health services doctor" who recommended that she undergo an evaluation by a primary care provider. *Id.* Dr. Carman assessed Ms. Porcello with left shoulder pain and referred her to an orthopedist. *Id.* at 9.

On March 20, 2017, Ms. Porcello presented to Dr. Marie Walcott at Agility Orthopedics with a complaint of left shoulder pain. Ex. 4 at 16-17. The medical note documenting this visit indicates that Ms. Porcello "developed left shoulder pain in

November after getting a flu shot” and that she’d seen her field hockey team’s physician, trainer, and primary care physician about her injury. *Id.* at 16. Ms. Porcello reported “developing weakness in her left shoulder and difficulty doing her training for field hockey.” *Id.* On examination, Dr. Walcott found that Ms. Porcello had full supple range of motion of her left shoulder. *Id.* at 17. It was also found that “[Ms. Porcello] has pain but intact strength with supraspinatus testing in the empty can position. She has pain and weakness with resisted external rotation.” *Id.* Dr. Walcott remarked “[i]t is unusual to have these symptoms after a flu shot and to last so long.” *Id.* Ms. Porcello was advised to get an MRI. *Id.*

Ms. Porcello underwent an MRI on her left shoulder on April 7, 2017. Ex. 4 at 18. It revealed “bone marrow edema in the superficial distal posterior aspect of the left humeral greater tuberosity with associated soft tissue and periosteal edema worrisome for chronic osteomyelitis.” *Id.*

Ms. Porcello returned to discuss her MRI results with Dr. Walcott on April 13, 2017. Ex. 4 at 20-22. Dr. Walcott observed that Ms. Porcello “continues to have significant pain when reaching to the side and reaching overhead.” *Id.* at 20. She also noted that Ms. Porcello had full supple range of motion in her left shoulder, pain and weakness with supraspinatus testing and external rotation, and was tender to greater palpation over greater tuberosity. *Id.* at 21. Referencing Ms. Porcello’s MRI, Dr. Walcott indicated “[t]he bright on T2, dark on T1 is likely either a contusion or a chronic osteomyelitis.” *Id.* Dr. Walcott explained that the MRI was reviewed with both a radiologist and tumor specialist who agreed with her assessment. *Id.* It was noted that a tagged white blood cell scan or a biopsy would be needed to rule out infection. *Id.*

In a medical note dated April 26, 2017, Dr. Walcott indicated that after reviewing Ms. Porcello’s MRI and lab results with “Dr. Olans from infectious disease,” this individual concluded that Ms. Porcello did not have osteomyelitis. Ex. 4 at 21. Dr. Walcott also stated that she reviewed the MRI and lab results with an unnamed “colleague in Boston” who believed that Ms. Porcello had a SIRVA. *Id.* Dr. Walcott concluded by indicating that she “reviewed the literature relating to this diagnosis and the MRI findings are similar to [Ms. Porcello’s].” *Id.* at 21-22.

On April 24, April 28, and May 1, 2017, Ms. Porcello presented to her college’s health services department concerning sinusitis. Ex. 8 at 1-6. Her shoulder was not mentioned during these visits. *Id.*

On April 27, 2017, Ms. Porcello’s mother, Cheri Porcello, sent an email to Sam Tarabelsi. Ex. 15. Although the recipient’s title is not given, it appears that he is associated with Dr. Carman’s medical practice. Ms. Cheri Porcello wrote that “from the day [my daughter] received the injection she has been complaining of arm/shoulder pain and weakness.” *Id.* She further wrote that her daughter was recently diagnosed with SIRVA. *Id.*

On May 9, 2017, Ms. Porcello returned to Dr. Carman for a follow-up visit. Ex. 2 at 1-5. In the medical note documenting this appointment it is noted that Ms. Porcello “developed left shoulder pain after flu vaccine last fall,” and that Dr. Walcott’s colleague, Dr. Lee, “suggested dx [diagnosis] is SIRVA (shoulder injury related to vaccine administration).” *Id.* at 1. It was further noted that Ms. Porcello has had left shoulder pain since November. *Id.* at 3. Additionally, Dr. Carman found that Petitioner “has had weakness [in her] left arm” and decreased strength in her left shoulder. *Id.* at 1, 3. While Dr. Carman offered to refer Ms. Porcello to Dr. Lee, who was noted to be familiar with SIRVA, she declined. *Id.* at 4.

Ms. Porcello presented to Dr. Walcott on June 5, 2017 “for follow-up of her left shoulder SIRVA.” Ex. 4 at 23. Ms. Porcello reported that her pain was improving, rating it as “5/10.” *Id.* Further, while she noted having discomfort when reaching overhead or lifting anything heavy, she was able to play field hockey. *Id.* Upon examination, Dr. Walcott found that Ms. Porcello had “[f]ull supple and symmetric range of motion.” *Id.* Dr. Walcott recommended that Ms. Porcello begin a short course of physical therapy with the ultimate goal of “regain[ing] fitness prior to starting field hockey this fall.” *Id.* at 24. Among the goals charted on the referral to physical therapy are “passive range of motion” and “active-assisted range of motion.” Ex. 18 at 4.

Ms. Porcello participated in physical therapy for her left shoulder from July 31 to August 16, 2017, completing six sessions. Ex. 18. On the intake form, Ms. Porcello indicated that the date of onset of her injury was November 11, 2017 – 11 days prior to vaccination. *Id.* at 15. However, when prompted to describe the cause of injury, Ms. Porcello wrote “I got the flu shot, months later told I had SIRVA, from the way the shot got injected.” *Id.*

On September 28, 2017, Ms. Porcello again presented to Dr. Walcott regarding her left shoulder. Ex. 10 at 1-2. It was noted that while Ms. Porcello’s strength was improving, she continued to have pain in her shoulder. *Id.* at 1. Dr. Walcott recommended that Ms. Porcello undergo a second MRI. *Id.* at 2.

Ms. Porcello returned to Dr. Walcott’s office to discuss the results of her MRI on October 5, 2017. Ex. 10 at 3. Dr. Walcott found that the MRI had “normalized.” *Id.* She also noted: “We discussed the findings of small partial-thickness infraspinatus tear. We discussed treatment for her shoulder pain, which may be coming from the partial tear versus the residual SIRVA.” *Id.* Ms. Porcello opted to forego having a cortisone injection but agreed “to work with physical therapy and do exercise program at home.” *Id.*

## **II. Affidavit Testimony Regarding Onset**

Although Ms. Porcello was vaccinated on November 22, 2016, there are no contemporaneous medical records that document her complaint of left shoulder pain until March 17, 2017 (almost *four* months later). Ex. 2 at 6. However, Ms. Porcello stated in her affidavit that “the pain began immediately after receiving the vaccination in my shoulder.” Ex. 1 at 1-2.

A witness affidavit submitted by a third party, Leah Marie Sullivan, states that she recalled Ms. Porcello having issues with her shoulder in the fall of 2016. Ex. 16 at 1. She noted “[w]e were both field hockey teammates so I noticed that Breana was unable to fully participate in practices and games.” *Id.* at 1-2. Ms. Sullivan also remarked on Ms. Porcello’s initial attempts to “determine what caused the injury”, stating “[t]his was a frustrating process that really required a lot of patience on [Ms. Porcello’s] part because of all the unanswered questions initially about the cause of the injury.” *Id.* at 2.

A witness affidavit was also submitted by Mackenzie Anne Foley, Ms. Porcello’s teammate and roommate. Ex. 17. In it she recalled that Ms. Porcello suffered from a shoulder injury “late 2016 through 2017.” *Id.* at 1. Like Ms. Sullivan, Ms. Foley also acknowledged the difficulty in establishing the cause of Ms. Porcello’s injury. She explained that “when [Ms. Porcello] told me she was having pain I tried to help her recall what she could have done to hurt herself. She cold [sic] recall nothing substantial that would cause the pain.” *Id.* at 1-2.

As previously noted, Ms. Porcello also submitted an affidavit from Hilary Ann Turner, her college’s certified athletic trainer. Ex. 13. In addition to recalling Ms. Porcello’s complaint of left shoulder pain in January 2017, Ms. Turner also noted her attempt to figure out the source of Ms. Porcello’s injury. *Id.* at 2. She explained that Ms. Porcello “did not have a specific mechanism of injury related to sports. When I pressed further into what she did over the winter break that might have caused the pain she mentioned that she had received a flu shot.” *Id.* at 2.

### **III. Petitioner’s Expert Report**

In addition to medical records and affidavits, Ms. Porcello submitted an expert report authored by Dr. Jeffrey A. Dlabach. Ex. 14 (“Dlabach Rep.”). Dr. Dlabach did not set forth his areas of expertise or attach his curriculum vitae, however. *Id.*

In his report, Dr. Dlabach noted that his review of Ms. Porcello’s pre-vaccination records had not revealed any pre-existing injury, diagnosis or complaint related to her left shoulder. Dlabach Rep. at 2. He also noted that Ms. Porcello’s left shoulder MRI showed edema in the greater tuberosity and in the surrounding soft tissues and stated that these traits are consistently seen in SIRVA cases. *Id.* According to Dr. Dlabach, the edema in the greater tuberosity “was a result of the flu vaccine administration in the nonideal location resulting in bone contusion. As a result of the chronic inflammation a partial thickness tear of the infraspinatus tendon developed.” *Id.*

Dr. Dlabach concluded that, in his medical opinion, to a reasonable degree of medical certainty, “Ms. Porcello sustained a SIRVA as a result of her November 22, 2016 flu shot.” Dlabach Rep. at 2.

#### IV. Relevant Procedural History

Ms. Porcello filed her petition without medical records on September 14, 2017<sup>3</sup>. ECF No. 1. The parties subsequently spent several months in settlement negotiations, but reached an impasse in the fall of 2018. ECF No. 38. Thus, on November 20, 2018, Respondent filed his Rule 4(c) report (“Report”) asserting that this case was not appropriate for compensation under the terms of the Vaccine Act. Report at 1, ECF No. 40. In it, Respondent noted Petitioner’s almost four-month delay in seeking treatment. Report at 5. Respondent further argued that, “in order to sustain a Table claim for SIRVA, the condition must manifest as ‘shoulder pain and [a] limited range of motion,’” but Ms. Porcello’s orthopedist “always documented [her] as having a full range of motion.” *Id.* Lastly, Respondent argued that Ms. Porcello had not proven actual causation. *Id.* at 5-6.

Petitioner filed some additional records in an attempt to address Respondent’s concerns, but Respondent adhered to his objections. ECF No. 45. Thereafter, on May 22, 2019, Ms. Porcello filed a Motion for Summary Judgement (“Motion”), Memorandum of Law in Support of Motion for Summary Judgement (“Memorandum”) and Statement of Undisputed Material Fact (“Statement”) arguing that she had met her burden of proving that she is entitled to compensation under the Vaccine Act. ECF No. 47. Later that summer and into the fall, she filed Dr. Dlabach’s expert report as well as additional evidence regarding the onset of her injury. ECF Nos. 50-51; 53-54.<sup>4</sup> On January 6, 2020, Respondent filed his response to Petitioner’s Motion (“Response”) asserting that Ms. Porcello’s Motion should be denied and her claim dismissed for failure to demonstrate entitlement to compensation. Response at 10, ECF No. 60. The matter is now ripe for resolution.

#### V. Ruling on the Record vs Summary Judgement

Pursuant to Vaccine Rule 3(b)(2), special masters are responsible for “mak[ing] the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master’s decision.” Under Vaccine Rule 8(d), a special master “may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgement, in which event the procedures set forth in RCFC 56 will apply.”

As I have previously observed (relying on controlling Federal Circuit precedent), “a special master’s ability to decide a case based upon written submissions without a hearing *is not limited* to a motion for summary judgement.” *Smallwood v. Sec’y of Health*

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<sup>3</sup> On December 6, 2017, Petitioner filed an amended petition to clarify that she was the recipient of a collegiate academic scholarship. ECF No. 14.

<sup>4</sup> On May 29, 2020, Petitioner filed a duplicate copy of her physical therapy records. ECF No. 61. These records were originally filed on September 12, 2019. ECF No. 56.



& Human Servs., No. 18-0291V, 2020 WL 2954958, at \*7 (Fed. Cl. Spec. Mstr. Apr. 29, 2020) (emphasis added), citing *Kreizenbeck v. Sec’y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020). Instead, “Rule 8(d) contemplates that special masters can decide cases on written submissions *other* than motions for summary judgement.” *Kreizenbeck*, 945 F.3d at 1366. (emphasis in original). Citing Vaccine Rule 3(b)(2), the *Kreizenbeck* court explained that special masters may rule on the record after affording the parties “a full and fair opportunity to present its case.” As noted in *Smallwood*,

such a ruling makes evidentiary determinations based on the parties’ submissions, and in so doing may weigh competing arguments about what conclusions are preponderantly supported by the evidence. A ruling on the record is thus distinguishable from a summary judgement determination, that presumes facts in the non-movant’s favor and only involves determining questions of law.

*Smallwood*, 2020 WL 2954958, at \*7. By contrast, a summary judgment motion is more appropriate when a party “believe[s] at an early stage of the proceedings that no material facts are in dispute and they will prevail as a matter of law.” *Kreizenbeck*, 945 F. 3d at 1366.

Although Petitioner styles her present motion as one for summary judgment, I find at this stage in the proceedings (and given the extensive factual materials filed) that it is best treated as requesting a ruling on the record. The record in this case is fully developed, and the parties have been afforded a full and fair opportunity to present their evidence and arguments. In order to resolve the motion and determine if in fact Petitioner should receive a damages award, I must weigh the evidence – a task I am empowered to perform without hearing, but which goes beyond the more limited judicial determinations implicit to the summary judgment process. Accordingly, I treat Petitioner’s motion as one requesting a ruling on the record (and to the extent it is not, I DENY the motion for summary judgment, so that I may instead evaluate the evidence overall).

## **VI. Actual Causation**

A petitioner may prevail on her claim if she has “sustained, or had significantly aggravated, any illness, disability, injury, or condition” set forth in the Vaccine Injury Table (“Table”). Section 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3(c)(10), identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). If a petitioner establishes she has suffered a “Table injury,” causation is presumed. However, when a petitioner has suffered an injury that either is not listed in the Table or did not occur within the prescribed timeframe, she must prove that the administered vaccine caused injury in order to receive Program compensation. Section 11(c)(1)(C)(ii) and (iii). Effective for petitions filed beginning on March 21, 2017, a SIRVA is an injury listed on the Vaccine Injury Table. See Vaccine Injury Table: Qualifications and Aids to interpretation (“QAI”). 42 C.F.R. § 100.3(c)(10).

While Ms. Porcello asserted a Table claim for SIRVA in her amended petition, she took a different stance in her Motion and, without explanation, has conceded that she did not suffer a Table injury.<sup>5</sup> Memorandum of Law at 5, ECF No. 47-1. Therefore, Ms. Porcello must prove her claim by showing that her injury was “caused-in-fact” by the vaccine in question. Sections 13(a)(1)(B) and 11(c)(1)(C)(ii). In such a situation, the presumptions available under the Table are inoperative, and the burden is on Ms. Porcello to introduce evidence demonstrating that the vaccination actually caused her shoulder injury. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of “causation-in-fact” must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. Section 13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525.

Under that standard, a petitioner must show that it is “more probable than not” that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. A petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a “substantial factor” in causing the condition, and was a “but for” cause. *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Based upon the above, Ms. Porcello must show by preponderant evidence that her November 22, 2016 vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for her injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen*, 418 at 1278 (citations omitted). All three prongs of *Althen* must be satisfied. *Id.*

#### **a. Analysis**

While I find that while Ms. Porcello is able to satisfy the first and second *Althen* prongs, she has failed to satisfy all three – as she must do to prevail.

##### **i. *Althen* Prong One**

Under *Althen* prong one, there must be preponderant evidence of a medical theory causally connecting Ms. Porcello’s vaccination to her injury. To satisfy this prong, Petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 548-49. Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d

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<sup>5</sup> As discussed in VI(a)(iii), below, Ms. Porcello would not have been able to sustain a Table claim for SIRVA in any event, because she failed to present preponderant evidence that she experienced onset of left shoulder pain within 48 hours of her November 22, 2016 vaccination.



1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1325–26 (Fed. Cir. 2006)).

In his expert report, Dr. Dlabach asserts that Ms. Porcello’s left shoulder MRI “revealed edema in the greater tuberosity, as well as surrounding soft tissues” and that this is a “consistent and diagnostic finding that is consistently seen in shoulder injury related to vaccine administration (SIRVA).” Ex. 14 at 2. Although Dr. Dlabach does not provide any additional explanation as to the mechanism of injury, I do find that Ms. Porcello has provided a “reputable medical theory.” *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006)(citations omitted).

Furthermore, while it is Ms. Porcello’s burden to establish all *Althen* prongs by preponderant evidence, Respondent has not disputed that the flu vaccine can cause SIRVA. It is also worth noting that there is a well-established track record of SIRVA compensation awards in non-Table cases (although settled cases are not particularly strong evidence). See, e.g. *Loeding v. Sec’y of Health & Human Servs.*, No. 15-740V, 2015 WL 7253760 at \*1 (Fed. Cl. Spec. Mstr. Oct. 15, 2015)(noting that “respondent ‘has concluded that petitioner’s injury is consistent with SIRVA; that a preponderance of evidence establishes that her SIRVA was caused in fact by the flu vaccination she received on October 14, 2014; and that no other causes for petitioner’s SIRVA were identified’”); see also *Johnson v. Sec’y of Health & Human Servs.*, No. 16- 165V, 2016 WL 3092002 (Fed. Cl. Spec. Mstr. April 13, 2016) (awarding compensation for a SIRVA caused-in-fact by the influenza vaccine); *Koenig v. Sec’y of Health & Human Servs.*, No. 16-1496V, 2017 WL 6206391 (Fed. Cl. Spec. Mstr. April 13, 2017)(same).

Accordingly, Ms. Porcello has preponderantly satisfied *Althen* prong one.

## ii. *Althen* Prong 2

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” an injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280).

Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records and/or statements of a treating physician’s views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. See § 13(b)(1) (providing that “[a]ny such diagnosis, conclusion,

judgment, test result, report, or summary shall not be binding on the special master or court.”)

The medical record for this case does not contain statements from Petitioner’s primary care provider concluding directly that Petitioner’s injury was caused by the flu shot, but instead relied on Dr. Walcott’s findings. See Ex. 2 at 1 (noting that Petitioner “had evaluation by Dr. Walcott – April 2017 – showed bone bruise.”). These findings in turn were largely based on a suggestion put forth by Dr. Walcott’s colleague. While her initial plan for treating Ms. Porcello included obtaining a tagged white blood cell scan to rule out infection, Dr. Walcott later noted that she had reviewed Ms. Porcello’s MRI and lab results with “a colleague in Boston who thought it was SIRVA.” Ex. 4. at 21-22. Dr. Walcott then reviewed literature related to this condition and found “the MRI findings are similar.” *Id.* at 22. However, without any additional explanation, Dr. Walcott’s medical notes indicate that her colleague’s opinion was, in fact, adopted: in documenting Ms. Porcello’s next appointment, Dr. Walcott stated that Petitioner returned to the clinic “for follow-up of her left shoulder SIRVA.” *Id.* at 23. It thus appears that Dr. Walcott’s diagnosis was the result of her consultation with an individual who had neither physically examined Petitioner nor reviewed Petitioner’s medical history. There is no indication that Dr. Walcott meaningfully assessed the cause of Ms. Porcello’s reported shoulder pain.

Dr. Dlabach also concluded that Ms. Porcello sustained a SIRVA as a result of her November 22, 2016 flu shot. Ex. 14 at 2. However, aside from noting that Petitioner’s “MRI revealed edema in the greater tuberosity, as well as surrounding soft tissues,” and stating that “[f]ollow up MRI revealed the resolution of the edema in the greater tuberosity that was a result of the flu vaccine administration in the nonideal location resulting in bone contusion,” Dr. Dlabach does not address causation in any detail. “A special master is not required to rely on a speculative opinion that ‘is connected to existing data only by the *ipse dixit* of the expert.’” *Isaac v. Sec’y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at \*17 (Fed. Cl. Spec. Mstr. July 30, 2012); quoting *Synder v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009). Accordingly, while his opinion is helpful to Petitioner, it does not stand as particularly robust support for her claim.

The next question is whether the medical records support Petitioner’s contention that she experienced a SIRVA injury. In prior cases where a SIRVA has been addressed as a cause-in-fact-claim, the QAIs governing the Table Injury of SIRVA have nevertheless been found to be persuasive guidance in establishing whether there is a logical sequence of cause and effect leading to a SIRVA. See, e.g., *Portee v. Sec’y of Health & Human Servs.*, No. 16-1552V, 2018 WL 5284599, at \*10 (Fed. Cl. Spec. Mstr. Sept. 14, 2018); *Capasso v. Sec’y of Health & Human Servs.*, No. 17-0014, 2018 WL 5077781, at \*5 (Fed. Cl. Spec. Mstr. August 3, 2019). The criteria under the QAI are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination

findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

82 Fed. Reg. 6303 (Qualifications and Aids to Interpretation for SIRVA).

Nothing in Ms. Porcello's prior medical history suggests any relevant history of pain, inflammation or dysfunction of her left shoulder. Moreover, I find no evidence that her pain and reduced range of motion extended beyond her left shoulder. Respondent has not suggested, nor do I find, that any other condition is present that could explain Ms. Porcello's reported injury. Accordingly, and although the evidence is not particularly robust on this point, I find that Petitioner has established that she did likely experience a SIRVA injury, and that it is preponderantly associated with her vaccination.

### iii. *Althen* Prong 3

The question of when Petitioner's shoulder pain first manifested, and whether that time frame is medically acceptable, is the primary basis for Respondent's recommendation against compensation in this case. Report at 5. Under *Althen* Prong three, there must be a proximate temporal relationship between vaccination and injury. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Ms. Porcello must therefore show that her injury did not occur too soon or too long after vaccination. *Id.*

The Table version of a SIRVA claim requires establishing onset of symptoms within 48 hours or less of vaccination. 42 C.F.R. § 100.3(c)(10). Although this is admittedly a causation-in-fact claim, the medical science supporting this onset period has been deemed persuasive even in cases alleging a non-Table claim. See *Almanzar v. Sec'y of Health & Human Servs.*, No. 16-0340V, 2018 WL 4042365, at \*7 (Fed. Cl. Spec. Mstr. April 20, 2018) (employing SIRVA Table criteria to find that the onset of symptoms within 48 hours of vaccination is a medically accepted timeframe for which to infer causation). It is therefore reasonable to keep that timeframe in mind even in a non-Table case. A petitioner as here asserting a non-Table SIRVA claim may not need to meet this fact issue to prevail, but *will* need to demonstrate a medically acceptable onset – and in so doing will need to pay some heed to the prevailing scientific view of when SIRVA claims are most likely to manifest.

As a result, timeframes for a non-Table SIRVA onset that is too long or short, relying on the Table timeframe as a general "yardstick," have failed. See, e.g., *Mack v.*

*Sec'y of Health & Human Servs.*, No. 15-0149V, 2016 WL 5746367, at \*11 (Fed. Cl. Spec. Mstr. July 14, 2016) (onset of six months is not evidence of a proximate temporal relationship for non-Table SIRVA claim). By contrast, in *Jewell v. Sec'y of Health & Human Servs.*, 2017 WL 7259139, at \*3 (Fed. Cl. Spec. Mstr. Aug. 4, 2017), former Chief Special Master Dorsey explained that while she was unable to find that the petitioner had experienced the onset of her shoulder injury within 48 hours “as required by the current Table,” the onset of her injury within 72 hours was nevertheless “a medically appropriate temporal relationship.” *Id.*

In Ms. Porcello’s case, based on the earliest date of record proof, the time between vaccination and onset appears to be more than three months. Ms. Porcello avers, however, that the onset of her left shoulder pain occurred *immediately* after receiving the flu vaccination in the same shoulder. Ex. 1 at 1-2. This is echoed in her mother’s April 27, 2017 email, in which it is noted that Ms. Porcello “has been complaining of arm/shoulder pain and weakness” from the day she received the flu shot. Ex. 15.

In reaction, Respondent observes that Ms. Porcello did not seek treatment for her left shoulder “until likely sometime in March 2017, at a minimum three months and one week after vaccination.” Report at 5. There is also no contemporaneous record documentation of injury in the immediate days following Ms. Porcello’s vaccination. Indeed, while Hillary Ann Turner submitted an affidavit stating that she remembered Ms. Porcello complaining of left shoulder pain that had begun “in late 2016”, the only evidence from this period is a January 18, 2017 doctor’s note that does not mention this ailment. Exs. 13 at 2; 3 at 4-5. Not until March 17, 2017 is Ms. Porcello’s injury documented “in real time.” Ex. 2 at 6.

The lack of reliable and persuasive record proof confirming an onset reasonably close in time to vaccination is compounded by Petitioner’s vague descriptions of the onset of her pain, and her initial inability to identify her vaccination as its source. Thus, some records only indicate that Petitioner’s shoulder pain began “in November” or some unspecified amount of time subsequent to vaccination. For instance, when Ms. Porcello first presented to Dr. Carman in March 2017, she reported having had arm pain “since she got the flu shot in November.” Ex 2 at 6, 7. See *also* Ex. 4 at 16 (noting that Ms. Porcello “developed left shoulder pain in November after getting a flu shot”); Ex. 2 at 1 (stating “patient developed left shoulder pain after flu shot last fall . . .”). But the only precise date that Ms. Porcello mentions is November 11, 2016 – 11 days *prior* to vaccination. See Ex. 18 at 15 (reporting the date of onset on her July 31, 2017 physical therapy intake form).

Petitioner has attempted to bolster her claim that her shoulder pain began immediately after vaccination by obtaining affidavits from Leah Marie Sullivan and Mackenzie Anne Foley, who were her former field hockey teammates. Exs. 16, 17. However, although both recall that Ms. Porcello experienced issues with her shoulder “in fall 2016,” associating her symptoms with an entire season, spanning several months, lacks the precision needed to determine whether the onset of Petitioner’s injury occurred

within a medically acceptable time frame. Further, their statements indicate that at least some time had passed between vaccination and the onset of Petitioner's pain, as they both recall their attempts to help Ms. Porcello identify a triggering event.<sup>6</sup> Additionally, Dr. Dlabach's expert report does not shed any light on the issue of onset. Ex. 14. Instead, it is merely noted that "[r]ecords indicate development of left shoulder pain." *Id.* at 2.

I acknowledge that the standard applied to SIRVA claims on the onset issue is fairly liberal (at least in the Table context), and will often permit a determination that onset began within the 48-hour timeframe set by the Table, based on records prepared a few months after vaccination, and/or corroborated by sworn witness statements intended to amplify otherwise-vague records. There are many situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking).

However, not every SIRVA claim can be so preponderantly established, and certainly not where witness affidavits contradict, or inadequately support, a petitioner's assertions of immediate onset. This case presents such circumstances. The evidence of when Petitioner's SIRVA began is vague, and in some cases contradicted by evidence suggesting a pre-vaccination start. In addition, Petitioner has *not* at all established what a reasonable timeframe for a non-Table SIRVA injury would be, as Dr. Dlabach's report is silent on this important question. As a result of these twin deficiencies, I cannot find that the timeframe for Petitioner's SIRVA was medically acceptable, and therefore the claim cannot succeed.

## VII. Conclusion

Having reviewed the medical records, expert report, and arguments put forth by the parties, I find that Petitioner has failed to offer preponderant evidence sufficient to satisfy the third *Althen* prong. **Therefore, the petition is dismissed for insufficient proof.**

The clerk is directed to enter judgement in accordance with this decision.<sup>7</sup>

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<sup>6</sup> Referring to Ms. Porcello's college's calendar of sports events from the fall of 2019, Respondent argues that Petitioner's vaccination was presumably administered after the *end* of the 2016 field hockey season, impacting the credibility of Ms. Sullivan's statement that Petitioner was unable to participate in practices and games. However, Respondent has not presented evidence of the field hockey schedule in place in 2016. See Response at 6.

<sup>7</sup> Pursuant to Vaccine Rule 11(a), entry of judgement can be expedited by each party filing a notice renouncing the right to seek review.



**IT IS SO ORDERED.**

**s/Brian H. Corcoran**

Brian H. Corcoran

Chief Special Master